

**REMARKS**

The Final Office Action of October 21, 2010, has been received and reviewed. Claims 1 through 16 are currently pending in the application. Claims 1 through 16 stand rejected. Applicant has amended claims 1 and 16, which amendments are supported at least by paragraphs [0016]-[0020] and [0036]-[0045] of the as-filed specification. No new matter has been added. With submission of the Request for Continued Examination, the Applicant respectfully requests reconsideration of the application as amended herein.

**35 U.S.C. § 103(a) Obviousness Rejections**

**Obviousness Rejection Based on U.S. Patent No. 6,071,274 to Thompson et al.**

Claims 1, 2, 3, and 8 through 15 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,071,274 to Thompson et al. (hereinafter “Thompson”). Applicant respectfully traverses this rejection, as hereinafter set forth.

To establish a *prima facie* case of obviousness, the prior art reference itself (or references when combined) or “the inferences and creative steps that a person of ordinary skill in the art would [have] employ[ed]” at the time of the invention must teach or suggest all of the claim elements. *K.S.R. Intern. Co. v. Teleflex Inc.*, 550 U.S. 398, 418, 82 U.S.P.Q.2d 1385 (2007); *see also* M.P.E.P. § 2143.03. Additionally, the Examiner must determine whether there is “an apparent reason to combine the known elements in the fashion claimed by the patent at issue.” *Id.* “[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.” *Id.* Further, rejections on obviousness grounds “cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *Id.* (quoting *In re Kahn*, 441, F.3d 977, 988 (Fed. Cir. 2006)). Finally, to establish a *prima facie* case of obviousness there must be a reasonable expectation of success. *In re Merck & Co., Inc.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986). Furthermore, the reason that would have prompted the combination and the reasonable expectation of success must be found in the prior art, common knowledge, or the nature of the problem itself, and not based on the Applicant’s disclosure. *DyStar Textilfarben GmbH & Co. Deutschland KG v. C. H. Patrick Co.*, 464 F.3d

1356, 1367 (Fed. Cir. 2006); MPEP § 2144. Underlying the obvious determination is the fact that hindsight cannot be used. *KSR*, 550 U.S. at 421; *DyStar*, 464 F.3d at 1367.

Thompson does not teach, suggest, or otherwise render obvious each and every element recited in independent claim 1, as currently amended. In particular, Thompson does not teach all elements recited by independent claim 1, including:

the shape-imparting element imparting a predetermined shape to the distal end of the tubular member when the distal end of the tubular member is extended beyond a distal end of the introducer, **the predetermined shape including a formation in a plane substantially orthogonal to the longitudinal axis of the introducer**, a distal end of the shape-imparting element extending beyond the at least one lumen of the tubular member and being anchored proximally a distal end of the introducer at a location external of the introducer, wherein, due, at least in part, to the anchoring of the distal end of the shape-imparting element to the introducer, **the formation is adjusted in the plane substantially orthogonal to the longitudinal axis of the introducer** in terms of an inner area of the predetermined shape in the plane substantially orthogonal to the longitudinal axis of the introducer, **when torsion is applied to the shape-imparting element**. (Emphasis added).

Thompson teaches a structure 100 carrying multiple electrode elements 28. Structure 100 is carried at the distal end 16 of a flexible catheter tube 12, as a part of a probe 10, as shown in FIG. 1. *See* Thompson, col. 13, lines 30-37. A sheath 102 is carried by the catheter tube 12, the sheath 102 including a distal section 104 extending about the multiple electrode structure 100. A short length of wire 106 is used to join the distal section 104 of the sheath 102 to the distal end 108 of the multiple electrode structure 100. *See* Thompson, col. 13, lines 45-57. It is noted that the Examiner has alleged the “core of the tubular member” corresponds to the shape-imparting member recited by claim 1. Office Action, page 2. As shown in FIG. 15A, among other figures, Thompson teaches the formation of a loop in a plane extending along the axis of the introducer, and not in a plane orthogonal to the longitudinal axis of the introducer. In addition, Thompson does not teach controlling the size of that shape in such an orthogonal plane. Instead, a loop is formed in the parallel plane by manipulating the catheter tube 12 to extend a member 20 out through a slot in a sheath 26. *See* Thompson, col. 10, lines 4-11.

While Thompson teaches that the “geometry of the loop structure 100 can be altered by varying either the stiffness or the length of the flexible wire 106, or both at the same time” (see

Thompson, col. 14, lines 50-52), Thompson, however, does not teach that such a geometry of the loop may be in a plane substantially orthogonal to the longitudinal axis of the introducer. In addition, the geometry may be altered by varying the stiffness or the length of the wire 106, but not by applying torsion to the shape-imparting element, as is recited in claim 1.

Therefore, Thompson does not teach, suggest, or otherwise render obvious all the limitations recited in independent claim 1. As a result, independent claim 1 would not have been obvious to a person of ordinary skill in the art at the time the invention was made considering Thompson. The Applicant respectfully requests that the Examiner withdraw the rejection of independent claim 1 under 35 U.S.C. § 103(a).

Claims 2, 3, and 8 through 15 depend from independent claim 1, which is allowable. Therefore, at least by virtue of their dependence from an allowable claim, claims 2, 3, and 8 through 15 are also allowable. The Applicant respectfully requests that the Examiner withdraw the 35 U.S.C. § 103(a) obviousness rejection to claims 2, 3, and 8 through 15.

Obviousness Rejection Based on Thompson in View of U.S. Patent Application  
No. 2001/0007070 to Stewart et al.

Claims 4 through 7 and 16 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Thompson in View of U.S. Patent Publication No. 2001/0007070 to Stewart et al. (hereinafter “Stewart”). Applicant respectfully traverses this rejection, as hereinafter set forth.

Claims 4 through 7 depend from independent claim 1. The teachings and deficiencies of Thompson are described above as they relate to independent claim 1. In addition, Stewart does not cure the deficiencies of Thompson.

In particular, Stewart teaches a catheter assembly 20 including a catheter body 22, a handle 24, and electrodes 26. Stewart, ¶ [0065]. Stewart further teaches:

The distal portion 32 extends from the intermediate portion 30 and forms a loop 34. In one preferred embodiment, the loop 34 is circular, formed in a plane transverse to the longitudinal axis L1. To this end, the distal portion 32 preferably includes a lateral segment 36. The lateral segment 36 extends in a generally lateral fashion from the intermediate portion 30. The loop 34 extends from the lateral segment 36 in an arcuate fashion, turning or revolving about a central loop axis C1 (shown best in FIG. 1B). Stewart, ¶ [0068].

While Stewart may teach a loop that is formed in a plane transverse to the longitudinal axis L1, as shown in FIGS. 1B and 1C, among other figures, the shape of the loop is fixed, and Stewart does not allow for shape control of the loop. In particular, Stewart does not teach shape control via anchoring the shape-imparting element to the introducer, let alone any formation that may be adjusted in the plane substantially orthogonal of the introducer, by applying torsion to the shape-imparting element.

Therefore, Thompson and Stewart, when combined, do not teach, suggest, or otherwise render obvious all the limitations recited in independent claim 1. In particular, the technical teachings of Thompson and Stewart are not sufficient to realize a practical arrangement embodying the limitations of claim 1. As a result, independent claim 1 would not have been obvious to a person of ordinary skill in the art at the time the invention was made considering Thompson in view of Stewart.

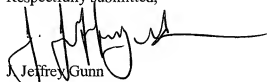
Therefore, at least by virtue of their dependence from an allowable claim, claims 4 through 7 are also allowable. The Applicant respectfully requests that the Examiner withdraw the 35 U.S.C. § 103(a) obviousness rejection to claims 4 through 7.

Independent claim 16 recites subject matter similar to that of claim 1 and is proposed to be amended in a manner similar to that of claim 1. As a result, the analysis presented above with respect to claim 1 in view of Thompson and Stewart is also applicable to claim 16. The Applicant respectfully requests that the Examiner withdraw the rejection of independent claim 16 under 35 U.S.C. § 103(a).

**CONCLUSION**

Claims 1 through 16 are believed to be in condition for allowance, and an early notice thereof is respectfully solicited. Should the Examiner determine that additional issues remain which might be resolved by a telephone conference, the Examiner is respectfully invited to contact Applicant's undersigned attorney.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "J. Jeffrey Gunn", with a long horizontal flourish extending to the right.

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Date: January 20, 2011  
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